REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of the claims

Claims 6, 8, 9, 11-15 and 17-30 were pending in the subject application, of which claims 20-22, 25 and 27-30[1] have been withdrawn from consideration by the Examiner. Claim 20 has been presently amended. However, no claims have been canceled or newly added with this submission. Hence, upon entry of this paper, the same claims will remain pending and under active consideration.

Specification

The specification has been amended to delete the word "or" from the paragraph commencing at line 25 of page 12, which word was mistakenly inserted during translation of the present application from Japanese.

Statement of the substance of an Interview

Undersigned counsel for Applicants wishes to thank Examiner Long for extending the courtesy of a telephonic interview on 26 January 2011 to discuss the outstanding rejections *vis-à-vis* the arguments presented below. The Examiner appeared to concede that such arguments would address the outstanding rejections and move the case to allowance.

Claim Rejections - 35 U.S.C. § 112

Written Description

Claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 stand rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully disagree.

In the paragraph that bridges pages 11-12, the specification provides that mesenchymal stem cells may be modified to comprise "genes with the function of increasing therapeutic effect" to improve the efficiency of therapy (*e.g.*, a preferred embodiment). The

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[1] According to the Office Action Summary, claim 27 is "withdrawn", which may be in error. In an Office Action dated 19 March 2008, claims 20-22, 25 and 28 were withdrawn, but not claim 27. In an Office

same paragraph goes on to provide explicit examples of such genes, namely: "(4) adding a substance that prolongs the lifetime of donor cells, or introducing a gene having the same effect (*e.g.*, the hTERT gene); … (10) adding a substance having neuroprotection activity, or introducing a gene having the same effect (*e.g.*, BDNF, GDNF, NT, NGF, FGF, EGF, or PFG); …(12) adding a substance having an antitumor effect, or introducing a gene having the same effect (e.g., IL-2 or IF-β)… ."[2] And, on page 13, lines 4-6, the specification provides that "preferred embodiments of the mesenchymal cells for use in the present invention are mesenchymal cells introduced with the BDNF gene, PLGF gene, GDNF gene, or the IL-2 gene."

The Examiner appears to suggest that in order to satisfy the written description requirement, the specification must provide a specific embodiment (*e.g.*, an "example") of a cell having both an hTERT vector and a vector comprising at least one of BDNF, GDNF, or IL12. The law on written description, however, does not impose such a strict requirement on the Applicant.

At the outset, "[a] description as filed *is presumed to be adequate*, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption."[3] All that is required to satisfy the written description requirement under Section 112 is a showing that "the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed."[4] Possession may be shown in any number of ways and, significantly, "need not be described literally."[5]

Applicants submit that one of ordinary skill in the art would, in fact, have reasonably concluded that Applicants' disclosure adequately described the claimed invention at the time of filing. hTERT expressing cells, for example, are disclosed throughout the specification

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Action dated 21 January 2010, claim 27 was indicated "withdrawn"—without explanation—even though it had been previously considered and not subsequently amended. Claim 27 does not stand presently rejected.

[2] Page 12.

[3] MPEP § 2163.04 (emphasis added). For this reason the Examiner "must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." *Id.*

[4] MPEP § 2163.02, entitled "Standard for Determining Compliance With the Written Description".

[5] *Id.*

and studied in Example 12 in the context of "immortalizing" a cell. As for the other genes recited in the claims, the specification teaches introducing BDNF or GDNF for "neuroprotection activity" and IL-2 for "antitumor effect" in mesenchymal cells.[6] And as noted above, the application lays plain the "preference" for a cells expressing "exogenous BDNF gene, PLGF gene, GDNF gene, or IL-2 gene in an expressible condition."[7]

Given this description, there can be no reasonable doubt that the person of ordinary skill in the art would have understood the Applicants to be in "possession" of a genetically engineered mesenchymal stem cell comprising a vector comprising a BDNF gene, PLGF gene, GDNF gene, or IL-2 gene, and a vector comprising an hTERT gene, *even assuming, arguendo*, the Examiner's position that the specification only provides specific embodiments of mesenchymal stem cell comprising a vector comprising either a BDNF, PLGF, GDNF, or IL-2 gene; or a hTERT gene. For, there is no teaching or suggestion in the art, let alone the specification itself, that the noted genes cannot co-exist in the same mesenchymal stem cell.

For at least these reasons, the present application adequately describes the claimed invention. Applicants respectfully request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 112.

Enablement

Claims 6, 8, 9, 11-15, 17-19, 23-24 and 26 stand rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner concedes that the specification is enabled for a mesenchymal stem cell comprising a vector comprising BDNF, PLGF, GDNF, or IL-2 gene. The Examiner further concedes that the specification is enabled for a mesenchymal stem cell comprising a vector comprising hTERT. Despite this disclosure, the Examiner alleges that the ordinary artist would have lacked sufficient information to make and use a mesenchymal stem cell comprising both a vector comprising a BDNF, PLGF, GDNF, or IL-2 gene; and a vector comprising hTERT gene. Applicants cannot agree.

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[6] Page 12, lines 23-24 and lines 27-28, respectively.

[7] Page 13, lines 6-8.

The test for enablement is not whether the prior art taught the subject matter being claimed,[8] but "whether [the] disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention."[9] On this point, "a patent need not teach, and preferably omits, what is well known in the art.[10]

There can be no disputing that at least as of 2003—the earliest claimed priority date of the present application—genetically engineering cells with transfection vectors had long become routine practice. What is more, although the Examiner has not opined on the record, the relative skill of those in the present art has traditionally been determined to be relatively high.[11] Taken together, there can be little reasonable basis in support of a notion that those of "high" skill in the art would not have known how to make a cell with two constructs, given a disclosure teaching cells with one construct. "As long as the specification discloses at least one method for making and using the claimed invention *that bears a reasonable correlation* to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied."[12]

Hence, the Examiner's allegation that the ordinary practitioner in the art would not have known how to "make and use" the claimed invention cannot be reasonably sustained. Withdrawal of the present rejections is respectfully solicited.

Request for rejoinder

Withdrawn claims 20-22, 25 and 27-30 depend from claims presumed to be in condition for allowance, making the withdrawn claims eligible for rejoinder. M.P.E.P. § 821.04 (further stating that "[t]he propriety of a restriction requirement[13] should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder.) Accordingly, Applicants respectfully solicit the rejoinder of claims 20-22, 25 and 27-30.

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[8] The Examiner notes, for example, "at the time of filing, the art [was] silent as to providing a mesenchymal stem cell [as claimed]."

[9] MPEP § 2164.01.

[10] *Id.*

[11] *See, e.g.*, MPEP § 2164.01(a) citing In re Wands.

[12] MPEP §2164.01(b)

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 27 January 2011

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[13] Office Action dated 19 March 2008.